MULTIPLE PROJECT ASSURANCE
(Revised June 1998)
Assurance of Compliance with Department of Defense Regulations for Protection of Human Research Subjects

[Institution Name] hereinafter known as the "institution," hereby gives assurance that it will comply with the Department of Defense (DOD) regulations for the Protection of Human Research Subjects (DOD Regulation 32 CFR 219, Part 1 and, where applicable, HHS Regulation 45 CFR 46, Subparts B, C and D), and Title 10, United States Code, Section 980 (hereinafter referred to as 10 USC 980) as specified below.

PART 1

Ethical Principles and Institutional Policies Governing Research Involving Human Subjects

I. Applicability

Except for research exempted or waived under the DOD regulations 32 CFR 219.101, and 10 USC 980, Part 1 of this Assurance applies to all research involving human subjects, and all other activities which even in part involve such research, regardless of whether the research is otherwise subject to federal regulation, if:

A. the research is sponsored by this institution, or
B. the research is conducted by or under the direction of any employee or agent of this institution in connection with institutional responsibilities, or
C. the research is conducted by or under the direction of any employee or agent of this institution using any property or facility of this institution, or
D. the research involves the use of this institution's nonpublic information to identify or contact human research subjects or prospective subjects.

II. Ethical Principles Governing Human Subjects Research

This institution is guided by the ethical principles regarding all research involving humans as subjects as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled, Ethical Principles and Guidelines for the Protection of Human Subjects of Research (the "Belmont Report") and as specified below.

A. This institution recognizes the principles of respect for persons, beneficence (including minimization of harms and maximization of benefits), and justice as stated in the Belmont Report and will apply these principles in all research covered by this Assurance.

B. This institution acknowledges and accepts its responsibilities for protecting the rights and welfare of human research subjects.

III. **Policies**

A. This institution acknowledges that it and its investigators bear full responsibility for the performance of all research covered by this Assurance, including full responsibility for complying with Federal, state, and local laws as they may relate to such research.

B. This institution assures that before human subjects are involved in research, proper consideration will be given to:

(1) the risks to the subjects,
(2) the anticipated benefits to the subjects and others,
(3) the importance of the knowledge that may reasonably be expected to result,
(4) the informed consent process to be employed,
(5) the provisions to protect the privacy of subjects, and
(6) the additional safeguards for vulnerable populations.

C. This institution recognizes the need for appropriate additional safeguards in research involving subjects who are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

D. This institution encourages and promotes constructive communication among the institutional officials, research administrators, department heads, research investigators, clinical care staff, human subjects, and all relevant parties as a means of maintaining a high level of awareness regarding the safeguarding of the rights and welfare of the subjects.

E. This institution will exercise appropriate administration overview carried out at least annually to assure that its practices and procedures designed for the protection of the rights and welfare of human subjects are being effectively applied.

PART 2

HUC, Institution, and Investigator Compliance with 32 CFR 219 and 45 CFR 46 and 10 USC 980

I. Applicability

A. Except for research in which the only involvement of human subjects is one or more of the categories exempted or waived under 32 CFR 219.101(b)(1-6) or 219.119 of DOD Regulations or 45 CFR 46.101(b)(1-6) or 46.101(e) of HHS Regulations, this policy is applicable to all research involving human subjects and all other activities which even in part involve such research, if either:

(1) the research is sponsored by this institution **or**
(2) the research is conducted by or under the direction of any employee or agent of this institution in connection with his or her institutional responsibilities, **or**
(3) the research is conducted by or under the direction of any employee or agent of this institution using any property or facility of this institution, **or**
(4) the research involves the use of the institution's nonpublic information to identify or contact human research subjects or prospective subjects.

II. Institutional Responsibilities

A. This institution acknowledges and accepts its responsibility to comply with the requirements of 32 CFR 219 Part 1, and 45 CFR 46 Subparts B, C, and D, and 10 USC 980, as specified below.

B. In accordance with the compositional and quorum requirements of 32 CFR 219.107 and 219.108, the HUC designated in the attached roster is responsible for the initial and continuing review of all research activities covered by this research.

C. This institute has provided and will continue to provide both meeting space for the HUC and sufficient staff to support the HUC's review and record keeping duties.

D. This institution acknowledges that it bears full responsibility for the performance of all research involving human subjects, covered by this policy, including continuing review of the research.

E. This institution encourages and promotes constructive communication among the research administrators, department heads, research investigators, clinical care staff, human subjects, and institutional officials as a means of maintaining a high level of awareness regarding the safeguarding of the rights and welfare of human subjects in activities carried out under this assurance.

F. This institution will consider additional safeguards in research when that research involves prisoners, fetuses, pregnant women, children, individuals institutionalized as mentally disabled, other potentially vulnerable groups and human in vitro fertilization.

G. This institution shall provide each individual at the institution conducting or reviewing human subjects research (e.g., research investigators, department heads, research administrators, research reviewers) with a copy of this statement of ethical principles and policy.

III. HUC Review

A. The HUC shall review and have the authority to approve, require modification in, or disapprove research conducted under this policy before human subjects may be involved.

B. The convened HUC must review and approve all human subjects research.

C. The HUC must determine, in accordance with the criteria found at 32 CFR 219.111, and where applicable, 45 CFR 46 Subparts B, C, and D, and 10 USC 980, that protection for human research subjects are adequate.

D. The HUC must have the authority to suspend or terminate approval of all human subjects research in accordance with 32 CFR 219.113 for (1) non-compliance with 32 CFR 219, and this Assurance document or the HUC's requirements, and (2) for elimination of unexpected serious harm to subjects.

E. The HUC must determine that legally effective informed consent is obtained in a manner and method which meets the requirements of 32 CFR 219.116 and 219.117.

F. Continuing reviews by the HUC must be conducted at intervals appropriate to the degree of risk, but not less than once per year (32 CFR 219.109[e]). The HUC may be called into an interim review session by the Chairperson at the request of an HUC member or Institutional Official to consider any matter concerned with the rights and welfare of human subjects.

G. The HUC shall prepare and maintain adequate documentation of its activities in accordance with 32 CFR 219.115.

H. The HUC must report promptly to institutional officials and the Human Subjects Protection Division (HSPD):

(1) any serious or continuing noncompliance by investigators with the requirements of the HUC,
(2) any suspension or termination of HUC approval,
(3) any unanticipated problems or injuries involving risks to subjects or others, and

(4) any changes in this research activity which are reviewed and approved by by the HUC.

I. Where appropriate, the HUC will determine that adequate additional protections are ensured for fetuses, pregnant women, prisoners, and children as required under Subparts B, C, and D of 45 CFR 46 and 10 USC 980. The HUC will notify HSPD promptly when HUC membership is modified to satisfy the requirements at 45 CFR 46.304 and when the HUC fulfills its duties under 45 CFR 46.305(c).

J. The HUC will comply fully with the requirements of all applicable Federal policies and guidelines, including those concerning notification of sero-positivity, counseling, and confidentiality of subjects.

K. The HUC will comply fully with 10 USC 980 which states: if an individual cannot give his/her own consent, and there is no intent to benefit the subject, (for example, minors) he/she cannot be entered into a study. <u>This is legally binding and there will be no exceptions.</u>

IV. Research Investigator Reporting Responsibilities

A. Investigators acknowledge and accept their responsibility for protecting the rights and welfare of human research subjects for complying with all applicable provisions of this Assurance and 32 CFR 219, 45 CFR 46 and 10 USC 980.

B. Research investigators shall report promptly to the HUC proposed changes in this research activity and the changes shall not be initiated without HUC review and approval except where necessary to eliminate apparent immediate hazards to the subjects. Any change in the investigator or change to the protocol shall be reported to the HUC.

C. Research investigators shall report promptly to the HUC any unanticipated problems involving risks to subjects and others. Any serious and unexpected adverse event(s) shall be reported to the HUC and the HSPD.

PART 3

Certification of HUC Approval and Institutional Endorsement

The officials signing below assure that all research activities at this institution will be conducted in accordance with the requirements of Title 32, Part 219 and Title 45, Part 46 of the Code of Federal Regulations, 10 USC 980, and this Assurance document. A dated roster listing the current membership of the designated HUC is attached:

I. **Authorized Official** of the Institution Providing This Assurance

Signature:_____

Name:_____

Title:_____

Address:_____

_____

_____

Phone:_____ FAX:_____

II. **Human Use Committee Chair**

This institution authorizes the designation of its HUC for review of the project referenced in this Assurance.

Signature:_____

Name:_____

Title:_____

Address:_____

_____

_____

Phone:_____ FAX:_____

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- SPACE BELOW FOR DEPARTMENT OF DEFENSE -

All parts of this Assurance are in compliance with the requirements of Title 32, Part 219, Title 45, Part 46 of the Code of Federal Regulations, and 10 USC 980.

DOD Approving Official

Signature_____Date: _____

Name: Ms. Yvonne Higgins, Chief
Address: Human Subjects Protection Division (HSPD)
U.S. Army Medical Research and Materiel Command,
504 Scott Street
Fort Detrick, MD 21702-5012

Telephone #: 301-619-2165\2166
FAX #: 301-619-7803

ASSURANCE NUMBER: _____*

*This assurance expires_____and must be renegotiated with the HSPD, USAMRMC.

HUMAN USE COMMITTEE (HUC) MEMBERSHIP

NAME OF HUC AGENCY OR COMMAND_____

Address and Phone No Chairperson only _____

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Members' Names			Highest	Scientific	Affiliation
First	MI	Last	Degree	Specialty	w/Institution
(1)					
(2)					
(3)					
(4)					

(1) Denotes Chairperson (3) Denotes HUC alternates
(2) Denotes HUC members (4) Denotes non-voting HUC attendee
(expert or technical expertise)